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14. Additional Environmental, Safety, Health, and Quality Assurance (ES&H/QA) Functions

14.1 Senior Management Council

Members and Purpose

The advises the on Laboratory policies and oversees the effectiveness of activities and programs to implement these policies. The SMC is chaired by the Director and is composed of the , , , and LLNL . With respect to ES&H matters, the SMC periodically reviews Laboratory ES&H policies and reviews the effectiveness of their implementation.

14.2 ES&H/QA Working Group

The supports the SMC. The ES&H/QA Working Group is composed of:

- An Assurance Officer from each programmatic directorate
- The heads of the , , and
- The
- .

The Working Group is chaired by one of its members and reports to the chairman of the SMC. The Working Group's broad membership and close association with the SMC provide a key mechanism for review proposed ES&H policies and implementing effective ES&H guidance.

Activities and Functions

The Working Group helps to identify and address policy issues concerning environmental protection, safety, health, and quality assurance at LLNL. It provides a means for communicating policy issues to the Laboratory programs, providing a forum for program input, and for developing recommendations to the SMC.

The activities of the Working Group include but are not limited to:

- Responding to requests for reviews and studies from the ES&H/QA Council
- Addressing ES&H/QA issues raised by the programs and preparing recommendations for consideration by the ES&H/QA Council

- Reviewing generic or institutional ES&H/QA issues, and bringing these to the attention of the ES&H/QA Council with recommendations for policy change.

14.3 Programmatic Assurance Offices

Each AD appoints an who oversees ES&H activities within the directorate and reports to the AD or Deputy AD with direct access to the AD. The Assurance Manager provides oversight of the directorate's ES&H activities and assists the Program in developing plans and procedures to ensure all directorate activities comply with Laboratory and directorate ES&H policies. The Assurance Managers are members of the .

Assurance Review Office

The conducts independent, internal ES&H appraisals to assure that Laboratory ES&H policies and their implementation are consistent with Laboratory requirements, DOE Orders, and ES&H regulations. The ARO head reports to the

14.4 Quality Assurance and Control

LLNL has a that covers all hazardous materials, substances, and wastes, including their on-site transfer. The Laboratory's Assurance Program is documented in the defines the overall management of the LLNL QA Program for Hazardous Material Packaging and Transportation Safety (i.e., HMPT Safety Program). This *HMPT QA Plan* makes quality assurance a systematic approach to work-management as required by the *LLNL QA Manual.* As implemented, the *HMPT QA Plan* provides confidence that the HMPT Safety Program objectives are achieved with due consideration for ES&H protection.

Objective of the HMPT QA Plan

The objective of the *HMPT QA Plan* is to ensure Laboratory-wide compliance with applicable regulations and provide confidence that hazardous materials, substances, and wastes will be safely packaged:

- For shipping by commercial carrier, DOE, other government agencies, or LLNL
- As received at LLNL

- During on-site transfer.

How the HMPT Safety Program and the *HMPT QA Plan* Work Together

The and apply to all activities at Livermore and Site 300 that can affect the containment of hazardous materials, substances, and wastes in transportation. They apply to:

- The integrity of containers for shipping hazardous materials, substances, and wastes in the public domain
- The integrity of packaging in on-site transfers of hazardous materials, substances, and wastes custody
- The identification of hazardous materials, substances, and wastes in containers and packaging.

Note: The HMPT Safety Program does not apply to processing or storage of hazardous materials, substances, and wastes.

Principal Participants of the HMPT Safety Committee

,, and MDD are the principal participants of the .

Responsibilities of the Principal Participants

Each principal participant is responsible for performing HMPT Program work in accordance with a specific QA Plan. The Plans have been written as prescribed in the *HMPT QA Plan* to address the organization's HMPT Safety Program responsibilities, functions and requirements. (Refer to M-078-91, ; M-078-92, ; and M-078-92,)

Principal participants are responsible for monitoring activities related to their assigned categories of hazardous material to promote HMPT Safety Program compliance. As requested, they will advise participating LLNL groups on program and regulatory requirements and provide guidance in obtaining technical assistance (e.g., container design and design reviews).

MMS's Responsibilities

Specifically, is responsible for:

- Applying for container certification and shipping classifications for new explosives
- Packaging selected Category 1 Hazardous Materials hazardous materials
- Category 1 Hazardous Materials transportation per established practice and as requested

- Container selection
- Serving as the Laboratory interface with the DOE for DOE-furnished shipping of nuclear components and special assemblies.

HWM Division's Responsibilities

is responsible for:

- Applying for Category 2 Hazardous Materials container certification
- Packaging Hazardous Waste Management Division-generated
- Collecting Category 2 Hazardous Materials from
- Container selection
- Releasing loaded Category 2 Hazardous Material containers to the for shipping.

MDD's Responsibilities

is responsible for:

- Applying for container certification
- Receiving, packaging, and the transfer of Category 3 hazardous materials
- Providing transportation services for other categories, on a request basis.

Other

Other LLNL groups that might design, modify, request to procure, fabricate, maintain, or load a container for shipping, or package hazardous materials, substances, and wastes for transfer, must do so in accordance with the *HMPT QA Plan* and referenced regulations and standards. These functions are performed in accordance with a specific QA Plan, written as prescribed the *HMPT QA Plan*. However, a Plan is not required if container procurement is the only HMPT Program activity.

Specific requirements for principal participant QA Plans are specified in the *HMPT QA Plan*. Document control of QA Plans and supporting documents and procedures are also addressed in the participant QA Plans.

14.5 Quality Assurance Appraisals

Purpose and Time of QA Appraisals

The HMPT Safety Committee conducts of HMPT Safety Program participants to evaluate the state of the Program throughout the Laboratory. Each participant is investigated as often as stipulated in applicable

regulatory documents and, as a minimum, once every four years.

QA appraisals are planned, performed and reported (in writing) by teams of at least two members, who, as teams, have the appraisal (or auditing) experience and understanding of management necessary to perform credible investigations and evaluations of participants' HMPT Safety Program activities.

Written

Upon completion of investigations, the team submits a written Appraisal Report of its findings and observations (and any recommendations) to the , with a copy to the individual(s) responsible for the investigated work.

Responding to the Appraisal Report

The HMPT Safety Committee ensures that the individuals responsible for the investigated work document and execute acceptable plans of corrective action. The HMPT Safety Committee chairman closes out each QA appraisal in writing when the Appraisal Report has been accepted by the HMPT Safety Committee.

The HMPT Safety Committee follows up on corrective actions to ensure execution, documentation, and results as planned. The Committee reviews and accepts the documentation and results of each action, and may initiate independent verification of results. When an action item has been completed and accepted, the HMPT Safety Committee chairman closes out that item in writing.

HMPT Safety Program

The HMPT Safety Committee will, from time to time, arrange for qualified personnel from other institutions to perform appraisals of selected parts of the HMPT Safety Program. The purpose is to strengthen the LLNL HMPT Safety Program through interactions with experts working in hazardous material packaging and transportation, but under different institutional management systems. The HMPT Safety Committee ensures that the individuals responsible for work investigated by external appraisal teams document and execute acceptable plans of corrective action.

Inter-laboratory Peer Reviews

The and LLNL have agreed through a to a perform periodic reciprocal appraisals of the hazardous materials packaging and transportation programs. The appraisals shall be documented in a written report, and shall include recommendations or suggestions for improvement, when warranted. The HMPT Safety Committee ensures that the individuals responsible for work investigated by external appraisal teams are corrected.

14.6 Quality Assurance (QA) Records Control

Records meeting the definition of "" (see **Appendix A, Glossary**) are controlled under the Quality Assurance (QA) Plans for MMS, HWM Division, and MDD. Below is a summary of the QA records referred to the QA Plans:

- Approved current revision documents
- Evidence of formal work controls and QA Plan and System upkeep
- Results of work
- Other documentation as designated by the appropriate Division Leader.

for QA Records

In general, QA records are retained for a minimum of three years. The Division Leader, however, may issue directives limiting or extending the record retention period for specific records. are provided in the individual QA plans.

14.7 QA Records Files and File Maintenance

For MMS, the Division Leader establishes QA records files, specifies the types of QA records to be kept in each file, and designates the "Responsible Person" to maintain the QA Records File.

The HWM Division Leader is responsible for all QA records compiled by HWM. The Division Leader may delegate this responsibility to Group Leaders, as appropriate. Each Group Leader may designate a "Responsible Person" to maintain a QA Records File.

For are responsible for the QA records related to their assigned work, and the Division Leader is responsible for all other QA records. Each Group Leader establishes a QA Records File and designates a "Responsible Person" to maintain the file.

QA Duties of the

The "Responsible Person " who maintains the QA Records File, must at minimum:

- Check submitted records for date and issuer's signature, and identify or accept documents as QA records
- Index and file QA records in a manner that facilitates retrieval and prevents damage or loss
- Control the removal of from the file.

Additional requirements are described in the individual HMPT QA Plans (M-078-91, M-078-92, M-078-93).

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